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(54) Title: TWO PIECE MALE CONDOM CATHETER AND METHOD FOR MANUFACTURE

(57) Abstract

A male external condom catheter comprising a conical portion and a sheath portion, wherein the sheath portion is urethane having a thickness from between about 2 mils. to about 8 mils. A method for producing the male condom catheter which includes dipping a conical portion placed on a mandrel into a liquid-state urethane bath, withdrawing the mandrel such that a sheath portion forms from the conical portion along the mandrel, curing the mandrel including the conical portion and the sheath portion and repeating the dipping and curing until the desired thickness of the sheath portion is obtained. A release coating and an adhesive may also be applied to the sheath surface prior to removing the condom catheter from the mandrel.

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TWO PIECE MALE CONDOM CATHETER AND METHOD FOR MANUFACTURE

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to a male external catheter, or condom catheter, and more particularly, to an external male catheter including a bio-compatible polyurethane sheath integrally affixed to a polyvinylchloride conical portion and a method for making the male condom catheter.

2. Description of the Prior Art

It is well known that over-hydrated skin is more susceptible to penetration by chemical irritants, thus causing irritations of the skin such as rashes, sores, swelling and the like. Further, with the use of occlusive materials such as "nonbreathable" tapes used in wound dressings or extended wear external male condom catheters, it is known that moisture increases in the skin causes the skin to become soft or macerated which can lead to skin breakage upon tape or external catheter removal.

In connection with a male urinal device of the type using a urine collection receptacle worn on the body or near the body, it is common to use a sheath of flexible material placed over the penis and connected to the receptacle with a tube or other form of flexible conduit. Since urinal devices must be worn for extended periods of time, it is customary for the sheath of such devices to be flexible to allow for patient comfort. It is also desirable for the sheath to possess high moisture transmission properties because some patients develop skin irritations such as swelling, rashes, sores, etc. due to skin contact with excess moisture, nitrates and protein constituents from urine decomposition as well as from chemicals contained in commonly used materials known in the art, such as rubber latex, for example.

U.S. Patent No. 4,475,910, entitled *Male Condom Catheter Having Adhesive Transfer On Roller Portion*, to Conway et al. discloses a male urinal device having a laminated sheath with an inner layer of latex rubber and an outer layer of silicone rubber. Adhesive is stored between the inner and outer layers when the sheath is rolled. As the sheath is unrolled about a penis, adhesive is released from the outer layer and adheres to the inner layer. Upon pressing the sheath to the penis, a leak-free bond is created.

U.S. Patent No. 4,885,049, entitled *Method of Manufacture of an External Catheter for Male Urinary Incontinence*, to Johannesson (hereinafter " '049") discloses a method of making an external male urinal device having a body portion, including an internal adhesive component and an external cover layer; both are prefabricated components. This disclosure specifically avoids the use of components in a liquid state. Further, the body portion, or sheath, is manufactured as a soft, thin-walled single layer component, preferably latex or synthetic rubber.

U.S. Patent No. 5,376,085, entitled *External Urinary Catheter having Integral Adhesive Means*, to Conway et al. (hereinafter " '085") discloses a method of making a male external silicone catheter having an integral acrylic adhesive affixed to the catheter during processing. The adhesive must be of the type that at least partially cross-links with the silicone catheter during a vulcanization step which occurs when the silicone catheter is in contact with the adhesive. The silicone and the adhesive will contact the skin during use.

U.S. Patent No. 4,626,250, entitled *Male Urinary Collection System and External Catheter Therefor*, to Schneider (hereinafter " '250") discloses an external male urinal device and a method for making the same, wherein the catheter is formed in a dipping process which includes a preliminary step of stretching a pre-formed tubular member over a dipping form. The end of the tubular form which is to become a distal tapered opening is treated so that latex will not adhere thereto upon dipping the remainder of the tubular form in a latex bath to form the outer sheath. The adhesive pad is preferably a

synthetic or natural rubber and can also be improved with a minor proportion of polyacrylamide resin. These chemicals will come to rest on the skin upon application of the catheter to a patient.

It is known to those skilled in the art that many patients develop skin irritations including rashes, sores, overly tender skin etc. with physical exposure to latex or other natural rubber products, as stated hereinbefore, regardless of whether or not the contact between the skin and the latex is made directly or indirectly through an adhesive layer such as that disclosed by the '910 and '250 patents. Further, as rubber latex is opaque, it is difficult to detect any developing skin irritations until patient discomfort develops or when the sheath is removed.

The rubber latex sensitivity phenomenon appears to be affecting the product choices of clinicians and consumers. Silicone catheters, such as (CLEAR ADVANTAGE)™ by the Mentor Corporation, are of tremendous appeal to users because the skin beneath the condom catheter is visible through the sheath. However, some patients' skin also macerate due to low moisture transmission of the silicone. In order to address patients experiencing skin maceration accompanying the use of silicone condom catheters or to address allergic reactions to rubber latex condom catheters, it is desirable to utilize a catheter which exhibits high moisture transmission and a low level of chemicals inherent in the sheath material. Further, the cone portion must be flexible enough to withstand insertion of a connecting portion to the receptacle but yet be durable enough to withstand pressure due to excess urinary pressure which may accumulate within the catheter. It is further desirable that the sheath and the cone portion be integrally affixed to one another to eliminate leakage.

The present invention overcomes the apparent problems and attendant disadvantages associated with male condom catheters formed from rubber latex, other synthetic rubber products or silicone.

SUMMARY OF THE INVENTION

The present invention is directed to a male external condom catheter that addresses the incontinence management needs of male patients who are sensitive to rubber latex, silicone or other rubber materials. More particularly, the preferred embodiment of the present invention includes a condom catheter having a cone portion which is then dipped into a liquid-state polyurethane bath thus forming a sheath which is integrally affixed to the cone portion. The present device is particularly advantageous in that the polyurethane sheath effectively eliminates the skin irritation problems normally associated with rubber latex sensitivity and skin breakdown due to excess moisture. Another feature of the present device is that it retains the feel, structure and inherent flexibility characteristics of rubber latex, silicone or other rubbers. Still another feature is the clear colorless appearance desired by physicians and consumers. A release coating and an adhesive may also be applied to the sheath surface.

Still another feature of the present device is that the lowest practicle manufacturing limit for sheath thickness is less than half of the lowest pratical limit for standard silicone sheath thickness. The thinner polyurethane sheath of the present invention has increased "breathability," durability, user comfort and ease in examining skin condition beneath the sheath without sheath removal.

The present invention includes a method for making a male condom catheter device. The method comprises placing a cone portion having tube end opposing a cone end on a mandrel forming a mandrel set, dipping the mandrel set into a liquid-state polyurethane bath such that polyurethane coats the cone and extends onto the mandrel, curing the polyurethane coated mandrel set and repeating the dipping and curing steps to obtain a desired sheath thickness.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG.1 is a perspective view of a male condom catheter device of the present invention; and

FIG.2 is a flow diagram indicating the method for making the male condom catheter in accordance with the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to FIG.1, a male condom catheter in accordance with the present invention is designated generally as **10**. Device **10** is preferably comprised of a condom portion in the form of a sheath or a sleeve **15** integrally affixed to a conical portion **17** at cone **19**. Conical portion **17** more preferably includes cone **19** merging with a surge chamber/anti-kink mechanism **21** which then merges with a neck **23**. Neck **23** connects with a tube **24**. Surge chamber/anti-kink mechanism **21** may also serve as a backflow prevention device for tube **24**, which is then connected to a urine collection receptacle via flexible conduit or tubing (not shown) . It will be understood by those skilled in the art that device **10** is not limited to the particular embodiment illustrated, and that other combinations of elements including, but not limited to, constrictions and bulbous surge chambers can be added to device **10** without departing from the spirit and scope of the present invention. Such elements, including those illustrated in FIG. 1, may assume various shapes or be arranged in an order other than that illustrated.

As indicated in FIG.2, male condom catheter device **10** is made by placing conical portion **17**, which is typically supplied as a single piece PVC form from various suppliers including, but not limited to, F & M Plastics for example, onto a mandrel wherein the taper of cone **19** fits tightly against the mandrel, forming a mandrel set with the mandrel.

Other clear resilient materials are suitable for conical portion 19 such as silicone, polyurethanes, styrenebutadienes or other clear thermoplastic rubbers.

The mandrel set is then heated from between about 90 deg. C. to about 100 deg. C., most preferably about 95 deg. C. The mandrel set is heated for about 10 minutes. The heated mandrel set is dipped into a liquid-state polyurethane bath. The polyurethane bath is held at a temperature between about 18 deg. C. to about 24 deg. C., preferably about 21 deg. C. The mandrel set is dipped to a depth corresponding to a desired sheath length. Polyurethane utilized in the present embodiment is "AUKUFLEX A111"™ from Aukland Medical Plastics, Inc. Other polyurethane suitable for medical purposes may also be utilized. The mandrel set is then withdrawn from the bath at a predetermined rate such that a sheath is formed on the mandrel set. The predetermined rate of about 10 inches per minute is utilized in the present embodiment. This withdrawal rate forms a sheath thickness of about 1.75 mils.

The mandrel set including the sheath is cured by first heating and then by cooling to ambient temperature. In the present embodiment, curing is accomplished by heating the mandrel set including the sheath preferably from between about 80 deg. C. to about 100 deg. C. for a predetermined time, most preferably heating at about 90 deg. C. for about 20 minutes. It will be understood that there is no air current while heating takes place as the current will tend to disturb the integrity of the forming sheath. The mandrel set including the sheath is then cooled at room temperature for about 5 minutes. The mandrel set including the sheath may be dipped and cured multiple times until desired sheath thickness is achieved. The sheath thickness is preferably between about 1.75 mils. to about 9 mils., as sheaths having a thickness thinner than 1.75 mils. are prone to tearing and those thicker than 9 mils. will not possess the flexibility required for patient comfort. More preferably the sheath thickness is within the range from between about 2 mils. to about 8 mils., and most preferably between about 3 mils. to about 4 mils.

A release coating and an adhesive may also be applied to the sheath prior to removal of condom catheter **10** from the mandrel.

Polyurethane sheaths having a thickness from about 3 mils to about 4 mils possess a moisture vapor transmission rate substantially equivalent to that found with normal human skin perspiration. Uncovered skin has a moisture transmission rate of about 41.3 +/- 3.5 $ug/cm^2/min$. while a polyurethane sheath, having a thickness of about 8.5 mils., has a moisture transmission rate of about 41.23 $ug/cm^2/min$. Further, it was found that the moisture vapor transmission value for the present invention improves both comfort and function. For example, it was found that a moisture vapor transmission at least about equal to that found in skin, i.e., about 41 $ug/cm^2/min$. avoids both skin maceration and excess moisture retention in an adhesive layer on the sheath portion.

Additionally, the physical characteristics of the polyurethane sheath having a thickness from between about 3 mils to about 4 mils were compared to those of a standard silicone sheath having a thickness from between about 8 mils to about 9 mils. Both sheath types possess the desirable clear colorless quality. The table below summarizes those results.

TABLE 1

Test	Polyurethane Sheath	Silicone Sheath
Sheath Wall Thickness	3 - 4 mils	8 - 9 mils
Percent Elongation	792 - 1549*	300 (before break)
100% Modulus psi	223 - 331	208 - 354
Tensile at Break psi	826 - 3089*	800
Moisture Vapor Transmission	> 75**	38**

*Elongation/Tension testing instrument stopped at maximum elongation, 2 out of 12 samples did not break at maximum instrument elongation.

**The units represent grams/100 in^2/24 hours at 95% relative humidity.

The polyurethane sheath is up to about 5 times more stretchable and durable than the silicone sheath, as shown by the percent elongation and the pounds per square inch required to break the sheath upon stretching. Therefore, the polyurethane sheath is stronger, more moisture vapor transmissive and yet is less than half as thick as the silicone sheath.

This invention has been described herein in considerable detail in order to comply with the Patent Statutes and to provide those skilled in the art with the information needed to apply the novel principles and to construct and use such specialized components as required. However, while a particular embodiment of the present invention has been described in detail, it is to be understood that various alterations, modifications and substitutions can be made therein without departing from the spirit and scope of the present invention, as defined in the figures contained therein and in the claims which follow. For example, one skilled in the art will appreciate that the foregoing embodiment is capable of being produced using conical portions from other clear resilient materials such as PVC, silicone, polyurethanes, other clear thermoplastic rubbers such as styrenebutadienes or combinations thereof.

WE CLAIM:

1. A male condom catheter for use with a urine collection receptacle means, comprising:

(a) a conical portion of resilient material, having a tube end opposing a cone end; and

(b) a sheath portion of polyurethane integrally affixed to the cone end of the conical portion, the sheath having a thickness from between about 1.75 mils. to about 9 mils.

2. The male condom catheter of claim 1, wherein the sheath has a thickness from between about 2 mils. to about 8 mils.

3. The male condom catheter of claim 2, wherein the sheath has a thickness from between about 3 mils. to about 4 mils.

4. A male condom catheter having a conical portion and a sheath portion integrally affixed thereto, wherein the sheath portion comprises a clear resilient material having a moisture vapor transmission value of at least about 41 ug/cm^2/minute.

5. The male condom catheter of claim 4, wherein the clear resilient material is polyurethane.

6. A method for making a male condom catheter having a conical portion and a sheath portion, comprising the steps of:

(a) placing the conical portion on a mandrel, the mandrel and the conical portion forming a mandrel set;

(b) preheating the mandrel set from between about 90 deg. C. to about 100 deg. C.;

(c) dipping the mandrel set into a liquid-state polyurethane bath, the bath having a temperature from between about 18 deg. C. to about 24 deg. C.;

(d) withdrawing the mandrel set from the bath at a predetermined rate such that the sheath portion is formed on the mandrel set;

(e) curing the mandrel set from step (d); and

(f) repeating steps (c) through (e) until the sheath portion is a desired thickness.

7. The method of claim 6, wherein withdraw rate of step (d) is about 10 inches per minute.

8. The method of claim 7, wherein the desired thickness of the sheath portion is from between about 2 mils. to about 8 mils.

9. The method of claim 7, wherein the desired thickness of the sheath portion is from between about 3 mils. to about 4 mils.

10. The method of claim 9, wherein curing further comprises heating the mandrel set from step (d) at a temperature from about 80 deg. C. to about 100 deg. C. for a predetermined time and cooling the mandrel set for a time sufficient to reach ambient temperature.

11. The method of claim 10, wherein the predetermined time for heating is about 20 minutes.

12. The male condom catheter produced by the methods of either claims 6 or 11.

Figure 1

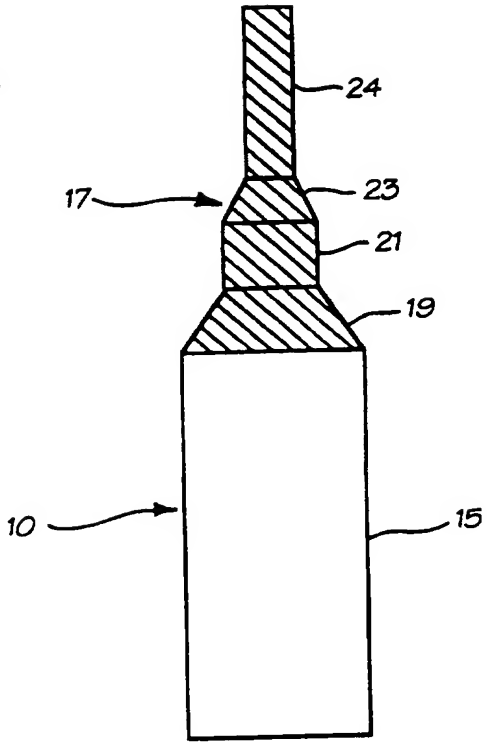
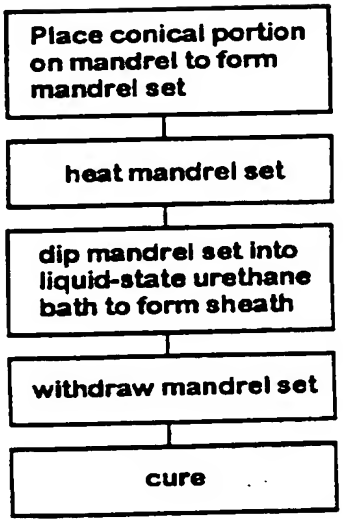


Figure 2



INTERNATIONAL SEARCH REPORT

Inter. nal Application No
PCT/US 95/07978

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F5/453

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classificaton symbols)
IPC 6 A61F

Documentaton searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US,A,3 520 305 (DAVIS) 14 July 1970 see column 3, line 41 - line 50 see column 4, line 12 - line 14 see column 4, line 70 - line 75; figures	1-3,5
Y	GB,A,2 152 380 (DOWNS SURGICAL PLC) 7 August 1985 see abstract	1-3,5
A	EP,A,0 335 564 (HOLLISTER INC) 4 October 1989 see column 3, line 26 - column 4, line 42 see column 5, line 42 - line 44; figures	6-12
A	GB,A,2 048 680 (CRAIG MED PROD LTD) 17 December 1980 see page 2, line 7 - line 28; figures	6-12

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Inter nal Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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E	EP,A,0 666 070 (SQUIBB & SONS INC) 9 August 1995 see column 2, line 47 - line 50	1

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INTERNATIONAL SEARCH REPORT

information on patent family members

Inter nal Application No
PCT/US 95/07978

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EP-A-0335564	04-10-89	US-A-	4932948	12-06-90
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III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
Y	US,A, 4,579,907 (WILDENAU) 01 April 1986. See column 1, lines 18-23, 37-43.	5,8,10 20,22
Y	US,A, 3,880,691 (PANNENBECKER ET AL) 29 April 1975. See column 2, lines 30-39, column 10, lines 25-39	20,21